K112532

HIOSSEN

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AUG 6 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date : Aug 31th, 2011

1. Company and Correspondent making the submission:

1) Submitter's Name :	HiOSSEN Inc.
2) Address :	85 Ben Fairless Dr. Fairless Hills PA 19030
3) Telephone No.	888 678 0001
4) Contact :	Mr. Patrick Lim

2. Device :

Trade or (Proprietary) Name :	ETIII Bio-SA Fixture System
Common or usual name :	Dental Implant
Classification Name :	Endosseous Dental Implant 21CFR872.3640 Class II DZE

3. Predicate Device :
The ETIII SA Fixture System, HiOSSEN Inc, K101096
The NanoTite PREVAIL Implant, Biomet 3I Inc, K072363
The Dio Biotite-H Implant System, DIO Department, DSI, Inc, K073070

4. Description :
1) The ETIII Bio-SA Fixture System is dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches. Fixture is made of pure titanium metal and supplied sterile. The surface treatment is Bio-SA.

2) ETIII Bio-SA Fixture is composed of single threads with internal hex connection taper body of bone level for two stage surgery. It has Bio-SA surface treatment.

3) ETIII Bio-SA Fixture is coated with nano thickness calcium phosphate on the SA surface of Al_2O_3 blasting & acid etching

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4) The ETⅢ Bio-SA Fixture System is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

5) The ETⅢ Bio-SA Fixture System is substantially equivalent in design, manufacturing process, function and intended use to the ETⅢ SA Fixture System (K101096) of HiOSSEN Inc, NanoTite PREVAIL Implant (K072363) of Biomet 31 Inc and Dio Biotite-H Implant System (K073070) of DIO Department, DSI, Inc.

- Substantial Equivalence Matrix

	ETⅢ Bio-SA Fixture	Predicate devices		
		ETⅢ SA Fixture (K101096)	**NanoTite PREVAIL Implant (K072363)**	**Dio Biotite-H Implant System (K073070)**
Manufacturer	HiOSSEN Inc.	HiOSSEN Inc.	Biomet 31 Inc.	DIO Department, DSI, Inc
Intended Use	The ETⅢ Bio-SA Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including ; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The ETⅢ Bio-SA Fixture System is for single and two stage surgical procedures. It is intended for delayed loading.	The ETⅢ SA Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including ; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The ETⅢ SA Fixture System is for single and two stage surgical procedures. It is not for immediate load.	BIOMET *3i* dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. BIOMET *3i* NanoTite dental implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.	The DIO Biotite-H Implant System is an endosseous dental implant that is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic appliance attachment to restore a patient's chewing function. Also, angled abutments on small diameter implants (3.8mm) of the DIO Biotite-H Implant System are intended for the anterior region of the mouth and not intended for the posterior region of the mouth due to possible failure of the implant.
Structure	-Single Thread -Taper body Type -Self tapping -Submerged fixture	-Single Thread -Taper body Type -Self tapping -Submerged fixture	-Single Thread -Straight body Type -submerged fixture	Morse taper with thread
Connection	Internal hex connection	Internal hex connection	Internal connection	Internal connection

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Type				
Diameter (D)	3.5~5.0	3.5~5.0	3.25~5.0	3.8~5.3
Length (mm)	7.0~15.0	7.0~15.0	8.5~15.0	8.0~14.0
Material of Fixture	Pure Titanium Grade 4 (ASTMF67-06)	Pure Titanium Grade 4 (ASTMF67-06)	Pure Titanium Grade 4 (ASTMF67-06)	Pure Titanium Grade 4 (ASTMF67-06)
Surface	Bio-SA	RBM	NanoTite	HA
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile	Radiation Sterile
S & E	The ETIII Bio-SA Fixture System has same material, indication for use and design as the ETIII SA Fixture System. But they have different surface treatment. The ETIII Bio-SA Fixture System has similar the surface treatment as the NanoTite PREVAIL Implant and the manufacturing process as the Dio Biotite-H Implant System			

5. Indication for use :
   The ETIII Bio-SA Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The ETIII Bio-SA Fixture System is for single and two stage surgical procedures. It is intend for delayed loading.

6. Review :
   The ETIII Bio-SA Fixture System has same material and indication for use and similar design and technological characteristics as the predicate device.

   The ETIII Bio-SA Fixture System has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Summary of nonclinical testing
   1) Fatigue testing was conducted according to the "Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment" with the worst case scenario of the GSIII Fixture and an angled abutment in support of the ETIII Bio-SA Fixture. The ETIII Bio-SA Fixture System has same material and similar design as the GSIII Fixture System.
   Therefore, the fatigue test result of GSIII Fixture System can be used as a proof of ETIII Bio-SA Fixture.
   2) The biocompatibility test was conducted according to ISO 10993-5, ISO 10993-6, ISO 10993-10 and ISO 10993-11. The results are in compliance with it.

8. Summary of clinical testing
   No clinical studies are submitted

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9. Conclusion :

Based on the information provided in this premarket notification HiOSSEN concludes that the ETⅢ Bio-SA Fixture System is substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Patrick Lim
Manager of Quality Assurance & Regulatory Affairs
Hiossen Incorporated
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

AUG 6 2012

Re: K112532
Trade/Device Name: ET III Bio-SA Fixture System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: July 17, 2012
Received: August 1, 2012

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number K _____

Device Name : ETⅢ Bio-SA Fixture System

Indication for use : ETⅢ Bio-SA Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including ; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. ETⅢ Bio-SA Fixture System is for single and two stage surgical procedures. It is intended for delayed loading.

Prescription Use___X____ (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____. (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena Green for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112532